CODAL-SYNTO

Joint effort

Moxarin®

Amoxicillin

MOXARIN® 500mg vials • **MOXARIN**® 1g vials

Summary of SPC for Moxarin®

Trade Name of the Medicinal Product:	Moxarin®
Qualitative and Quantitative Composition:	Each vial provides the equivalent of either 500mg or 1g amoxicillin as amoxicillin sodium E.P.
Therapeutic indications:	Treatment of infection such as: Upper respiratory tract infection; Otitis media; Bronchitis (acute and chronic); Lobar pneumonia and bronchopneumonia; Chronic bronchial sepsis; Bacteriuria in pregnancy; Cystitis, pyelonephritis, urethritis; Gynaecological infections (septic abortion, puerperal sepsis included); Gonorrhoea; Peritonitis and intra-abdominal sepsis; Septicaemia; Bacterial endocarditis; Typhoid and paratyphoid fever; Skin and soft tissue infections; Dental abscess in conjunction with surgical intervention; Prophylaxis of endocarditis.
Posology and Method of Administration:	Adults: 500mg every eight hours intramuscularly, or by slow intravenous injection if more convenient. In severe infections the dose should be increased to 1g given every six hours. Children (up to ten years old): 50mg - 100mg/kg body weight daily, in divided doses. Dosage in Renal Impairment: Mild renal impairment (glomerular filtration rate >30ml/min): dose every eight hours. Moderate renal impairment (glomerular filtration rate 10ml - 30ml/min): maximum 500mg every twelve hours. Severe renal impairment (glomerular filtration rate <10ml/min): maximum 500mg every twenty four hours.
Contra-indications:	Patients hypersensitive to penicillins.
Special Warnings and Precautions for Use:	Cross sensitivity to amoxicillin can exist in patients who are sensitive to cephalosporins or griseofulvin. The possibility of supra-infection exists. Patients using oral contraceptives. In patients also suffering from glandular fever a viral infection, such as Epstein Barr or Cytomegalovirus or acute lymphocytic leukaemia, there is a risk of rash with amoxicillin.
Interactions with other Medicaments and other forms of Interaction:	Allopurinol; Aminoglycoside antibiotics; Methotrexate; Oral contraceptives:
Pregnancy and Lactation:	It has been in widespread use worldwide since 1972, and clinical studies have documented the suitability for use in pregnancy. If administered during lactation, consideration should be given to discontinuation of breast feeding.
Undesirable Effects:	Hypersensitivity, allergic reactions, anaphylaxis; Diarrhoea, abdominal cramps, indigestion, nausea, pseudomembranous colitis; Decrease excretion of urinary phenolsulfonphthalein; Haemolytic anaemia, thrombocytopenia; Transient elevation of alkaline phosphatase, bilirubin and transaminases (SGOT, SGPT); Acute interstitial nephritis.
	MAH: Codal Synto Ltd.